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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,736	02/02/2001	Hirokazu Kubota	Q62542	6936

7590 04/09/2003

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/773,736	Kubota et al.
Examiner	**Art Unit**
Deepak Rao	1624

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 21, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-6, 8-10, 15, 16, 18, 19, and 21-43* is/are pending in the application.

4a) Of the above, claim(s) *8 and 18* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-6, 9, 10, 15, 16, 19, and 21-43* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This office action is in response to the amendment filed on January 21, 2003.

Claims 1, 3-6, 8-10, 15-16, 18-19 and 21-43 are pending in this application.

The following rejections are withdrawn:

The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments.

The rejections under 35 U.S.C. 102(a) and 102(b) of the previous office action are withdrawn in view of the amendments.

Election/Restriction

As provided in the previous office action, the examination was limited to a subgenus around the elected species by fixing the definitions of D, n, B and X as defined in the elected species (i.e., D is 1H-pyrazol-1-yl; n is 0; B is 1,4-phenylene; and X is -NH-CO-) and expanding the definition of A only, additional art was found. As per the guidelines of election of species, claims 8 and 18 (wherein D is 1H-pyrazol-5-yl); and the generic subject matter of the remaining claims, other than as indicated above; are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The following rejections are under new grounds:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 9-10, 15-16, 19, 21-36 and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the terms "Alk" and "Hal" that are not an art recognized abbreviations to represent any single group. For example, "Alk" unless specifically defined, could represent 'alkyl', 'alkenyl', 'alkynyl', etc. because all of these terms have the same prefix. A chemical dictionary provides that "Alk" is an abbreviation for (1) alkaloid, (2) alkyl. Similarly, "Hal" is also not a well recognized standard abbreviation in the art. It is suggested that a definition be provided for these terms as supported by the specification.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. (Indian Journal of Chemistry). The reference discloses pyrazol-1-yl compounds, see compounds 2, 3, 15 and 16 in a synthesis of preparation of other biologically active compounds. The reference also discloses that the synthesis involves solvents such as water, etc. and therefore, inherently teaches the disclosed compounds along with a carrier. Therefore, the instantly claimed composition reads on the reference composition as the intended use is not given patentable weight.

This rejection was made in the previous office action and applicant argued that the reference does not teach pharmaceutical properties for the intermediate compounds. This is not found to be persuasive because as can be seen from the full article, the reference inherently teaches that the compound in solution and the intended use is not given patentable weight.

2. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al., U.S. Patent No. 4,728,653. The reference discloses pyrazol-1-yl compounds (see compound 11 in col. 35) as an intermediate useful in the preparation of other pharmaceutically active compounds. The reference also teaches that the compounds are isolated in a solvent and therefore, inherently teaches the disclosed compound along with a carrier. Therefore, the instantly claimed

composition reads on the reference composition as the intended use is not given patentable weight.

3. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al., WO 85/04878. The reference discloses pyrazol-1-yl compounds (see compound c) in page 39) as an intermediate useful in the preparation of other pharmaceutically active compounds. The reference also teaches that the compounds are isolated in a solvent and therefore, inherently teaches the disclosed compound along with a carrier. Therefore, the instantly claimed composition reads on the reference composition as the intended use is not given patentable weight.

4. Claims 1, 3-6, 9-10, 15-16, 19 and 21-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Betageri et al., U.S. Patent No. 6,506,747 (effective filing date: June 5, 1998). The instantly claimed compounds read on reference disclosed compounds, see the structural formula I in col. 6 wherein L is -NH-CO- and the compounds disclosed in the Examples and the compounds of Table 1. The reference teaches that the compounds are useful in treating a variety of disorders including inflammatory diseases, autoimmune diseases, allergies, etc. see col. 18-19.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-10, 15-16, 19 and 21-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Betageri et al., U.S. Patent No. 6,506,747. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in col. 6 wherein L is -NH-CO- and the species of the Examples and compounds of Table 1. The compounds are taught to be useful as therapeutic agents for inflammatory diseases, etc., see col. 18-19. Claims 1, 3-6, 9-10, 15-16, 19 and 21-36 read on the compounds disclosed in the reference, see the rejection under 35 U.S.C. 102 above. The remaining claims differ from the

reference by reciting a specific species and/or a more limited genus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Receipt is acknowledged of the Information Disclosure Statement filed on January 21, 2003 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Deepak Rao
Primary Examiner
Art Unit 1624

April 4, 2003